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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/560,723 | 12/15/2005 | Richard Einstein | BJS-3665-166 | 5102 |
| 23117 7590 08/21/2009 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | | |
| EXAMINER | | | | |
| AEDER, SEANE | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1642 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 08/21/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,723

Applicant(s)

EINSTEIN ET AL.

Examiner

SEAN E. AEDER

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2, 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

The Amendments and Remarks filed 7/20/09 in response to the Office Action of 4/20/09 are acknowledged and have been entered.

Claims 1, 2, and 16 are pending.

Claim 2 has been amended by Applicant.

Claims 1, 2, and 16 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections.

Rejections Withdrawn

All previous rejections are withdrawn.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlegel et al (WO 01/60860 A2; 8/23/01).

Claim 16 is drawn to a diagnostic kit for detection of prostate cancer which comprises a nucleic acid according to claim 1 or claim 2 and a detectable label.

Schlegel et al teaches a 518 base pair nucleic acid prostate expression marker sequence which encodes the entire amino acid sequence of instant SEQ ID NO:183 (see sequence comparison below, in particular). Schlegel et al further teaches a kit comprising said 518 base pair nucleic acid sequence and a detectable label (see lines 15-23 of page 32, in particular).

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Pred. No.:      6.12e-07      Length:      518
Score:          90.00         Matches:     18
Percent Similarity: 100.0%    Conservative: 0
Best Local Similarity: 100.0% Mismatches:    0
Query Match:    100.0%        Indels:      0
DB:             5             Gaps:        0

```

Qy 1 ValGluThrGluPheHisArgValSerGlnAspGlyLeuAspLeuLeuThrSer 18
 |
Db 396 GTAGAGACGGAGTTTCATCGTGTAGCCAGGATGGTCTCGATCTCCTGACCTCG 449

Claims 2 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al (US 6,812,339 B1; 11/2/04).

Venter et al teaches a nucleic acid sequence, SEQ ID NO:115308, which encodes the entire amino acid sequence of instant SEQ ID NO:183 (see sequence comparison below, in particular). Venter et al further teaches a kit comprising SEQ ID

NO:115308 and a detectable label, wherein the detectable label is a SNP (see lines 16-22 of column 6, in particular).

| | | | |
|------------------------|---------|---------------|-----|
| Pred. No.: | 5.7e-07 | Length: | 601 |
| Score: | 90.00 | Matches: | 18 |
| Percent Similarity: | 100.0% | Conservative: | 0 |
| Best Local Similarity: | 100.0% | Mismatches: | 0 |
| Query Match: | 100.0% | Indels: | 0 |
| DB: | 3 | Gaps: | 0 |

US-10-560-723-183 (1-18) x US-09-949-016-115308 (1-601)

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Qy      1 ValGluThrGluPheHisArgValSerGlnAspGlyLeuAspLeuLeuThrSer 18
          ||||||||||||||||||||||||||||||||||||||||||||
Db      488 GTAGAGACGGAGTTTCACCGTGTTAGCCAGGATGGTCTTGATCTCCTGACCTCG 541
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Allowable Subject Matter

Claim 1 is allowed.

Summary

Claims 2 and 16 are rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642